

Message Text

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15

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-10 NEA-09 ISO-00 OES-05

EB-07 COME-00 CIAE-00 INR-07 NSAE-00 RSC-01 /074 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY: OES/SCI/BMP: MBEAUBIEN

DHEW/OIH/MACODDING

EUR/NSC/IG:JROUSE INFO

EA/RA:CCHAPMAN INFO

ARA/CEN:PWWACKERBARTH INFO

NEA/ARN:PKBULLEN INFO

AF/S:RJDOIS INFO

EUR/CE:BAFLATIN INFO

ARA/BR:AWATSON INFO

----- 030211

R 042240Z FEB 75

FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA

AMEMBASSY VIENNA

AMEMBASSY BRUSSELS

AMEMBASSY BRASILIA

AMEMBASSY SAN SALVADOR

AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY TOKYO

AMEMBASSY BEIRUT

AMEMBASSY THE HAGUE

AMEMBASSY PRETORIA

AMEMBASSY MADRID

AMEMBASSY BERN

AMEMBASSY DAMASCUS

AMEMBASSY BANGKOK

AMEMBASSY LONDON

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E.O. 11652: N/A

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TAGS: ETRD, EIND, TBIO, AS, AU, BE, BR, BS, FR, GW, JA,

LE, NL, SF, SP, SZ, SY, TH, UK

SUBJECT: INADEQUATELY LABELED MEDICAL DEVICE

1. FDA ADVISES THAT THE VITAL SIGNS MONITOR, MANUFACTURED BY BECKMAN INSTRUMENTS, INCORP. ADVANCED TECHNOLOGY OPERATIONS, 1630 SOUTH STATE COLLEGE BLVD. ANAHEIM, CALIFORNIA 92806, MODEL VSM-100 AND VSM-100B (IDENTICAL WITH VSM-100 EXCEPT FOR THE TRIM), SERIAL NOS. 1-181, 200001-200319 DISTRIBUTED FROM 12/8/69 - 10/74 ARE INADEQUATELY LABELED. THE VSM MONITOR IS AN ELECTRONIC DEVICE INTENDED FOR USE ON INFANTS AND MONITORS RESPIRATION, CARDIAC RATE, AND TEMPERATURE. THE DEVICES WHICH WERE SHIPPED IN INTERSTATE COMMERCE WERE LABELED INDICATING THAT THE PRODUCT WAS U.L. APPROVED AND WAS SAFE FOR USE WITH CARDIAC CATHETERS. THE DEVICES LACKED PRESCRIPTION LEGENDS. LEAKAGE OF CURRENTS AT THE CARDIAC ELECTRODES RANGE UP TO FOUR TIMES THE U.L. SPECIFICATIONS.

2. ON NOVEMBER 11, 1974, THE FIRM ISSUED A WARNING LETTER, TWO ADHESIVE LABELS, AND A PREPAID RETURN POST CARD TO CONSIGNEES. ONE OF THE ADHESIVE LABELS WAS TO BE APPLIED OVER A PAGE IN THE OPERATING MANUAL. A SMALLER CAUTION LABEL WAS TO BE APPLIED TO THE FRONT PANEL OF THE VSM-100 DEVICE ON THE LEFT SIDE JUST BELOW THE TEMPERATURE ALARM. THE DEVICES ARE NOT REPEAT NOT TO BE RETURNED TO THE MANUFACTURER.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO ASCERTAIN WHETHER OR NOT THEY HAVE RECEIVED THE WARNING LETTER ISSUED BY THE FIRM, THE TWO ADHESIVE LABELS, AND THE PREPAID RETURN POST CARD.

4. FOREIGN CONSIGNEES, AS FOLLOWS:

SELBY'S SCIENTIFIC LTD., 352-368 FERNTREE GULLY ROAD, NOTTINGHILL, MELBOURNE, VICTORIA, AUSTRALIA

BECKMAN INSTRUMENTS BMBH., STEFAN ESDERS - PLATZ 4 1191 VIENNA 19, AUSTRIA.

ANALIS, 14, RUE DEWEZ 5000, NAMOUR, BELGIUM.

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AMBRIEX, RUA CEARA, 103-2 E3 ANDARES, ZC-29, RIO DE JANEIRO, BRAZIL

DADA, S.A., APARTADO POSTAL 274, SAN SALVADOR, EL SALVADOR.

BECKMAN INSTRUMENTS FRANCE S.A., 52 CHEMINDES BOURDONS, GAGNY, FRANCE 93220.

BECKMAN INSTRUMENTS GMBH., FRANKFURTER RING 115, 8 MUNICH 40,
FEDERAL REPUBLIC OF GERMANY.

BECKMAN-TOSHIBA, LTD, TOKUEI BLDG., 33-7, SHIBA 5 - CHOME,
MINATO-KU, TOKYO, JAPAN.

BECKMAN MIDEAST TECHNICAL OFFICE, P.O. BOX 5910, BEIRUT, LEBANON.

BECKMAN INSTRUMENTS NEDERLANDS, P.O. BOX 47, MIJBERHEIDSWEG -
21, MIJDRECHT, NETHERLANDS.

BECKMAN INSTRUMENTS (PTY) LTD., TEMPLE HOUSE, 59/61 BUITENKANT ST.,
CAP TOWN, SOUTH AFRICA.

PACISA, GRAL. P. DE RIVERA 35, APARTADO 7023, MADRID 5, SPAIN.

BECKMAN INSTRUMENTS, RUE DES DIERRES - DU - NITRON 17, GENEVA,
SWITZERLAND.

GEORGES JAMAIL AWAD, P.O. BOX 237, RUE TAREK BEN ZIAD, DAMASCUS,
SYRIA.

CESCO, LTD., P.O. BOX 445, BANGKOK, THAILAND.

BECKMAN - R.I.I.C. LTD. TELFORD ROAD, EASTFIELD INDUSTRIAL
ESTATE, GLENROTHES, FIFE, SCOTLAND. KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CONSUMER PROTECTION, LABELING, MEDICAL CARE, EQUIPMENT
Control Number: n/a
Copy: SINGLE
Draft Date: 04 FEB 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE025629
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750041-1040
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750273/aaaacnkn.tel
Line Count: 141
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 16 APR 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <16 APR 2003 by RuthemTJ>; APPROVED <05 JAN 2004 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: INADEQUATELY LABELED MEDICAL DEVICE
TAGS: ETRD, EIND, TBIO, XX
To: CANBERRA MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006